REMARKS/ARGUMENTS

The pending office action addresses claims 1-21. Currently claims 1-21 stand rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,848,327 of Perdue.

Applicant's Invention

Applicant's invention relates to a device and method for verifying the proper alignment of a surgically implanted device with an image obtaining device, such as an X-ray machine. A key step in obtaining images that can tell the surgeon whether the implant is properly aligned within the patient is to properly align the imaging device itself. However, if upon viewing the image, the imaging device is not properly aligned for making the needed determination, its position is adjusted and a new image is obtained. This process of aligning the imaging device may be repeated multiple times if the implant is not correctly aligned. For well known reasons, it is preferable to minimize the patient's exposure to x-rays, as well as to take as few x-rays as possible during the procedure, rendering it desirable to minimize the time duration involved in the imaging verification step.

As shown in Applicant's FIG. 1, reproduced below, one embodiment of an alignment verification device 10 of the present invention is used to correctly align an image obtaining device 106 with a prosthetic device 102 placed surgically within a patient 120.

The alignment verification device 10, shown in Applicant's FIG. 2, also reproduced below, comprises a spacer element 12 having two elongate members 14, 16, and an alignment guide surface 40 defining an alignment orifice 42. The spacer element 12 has an insert engaging element 20 on its distal end which includes individual prosthesis engaging elements 22, 24 on a distal end of each of the elongate members 14, 16, respectively. Insert engaging element 20 interacts with prosthesis 102 to place alignment orifice 42 into a predetermined geometric relationship with, and spaced apart from, the prosthesis 102 so that sighting element 108 can be aimed through alignment orifice 42 to strike a predetermined visual indicator point 26 to provide a visual indication that image obtaining device 106 (FIG. 1) has been placed in a known orientation with respect to prosthesis 102, allowing verification of the orientation of the prosthesis to proceed efficiently.

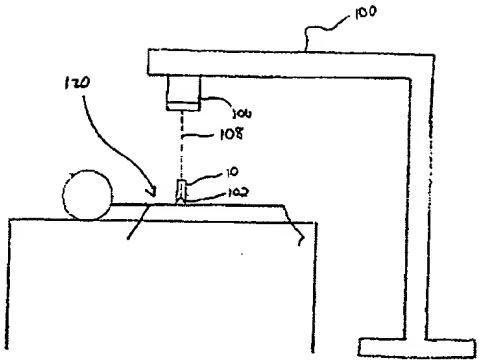


FIG. 1

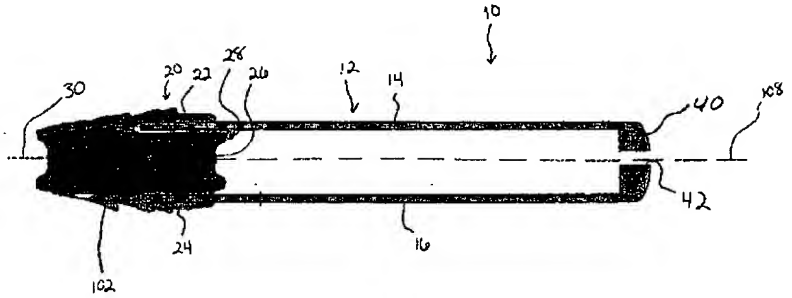


FIG. 2

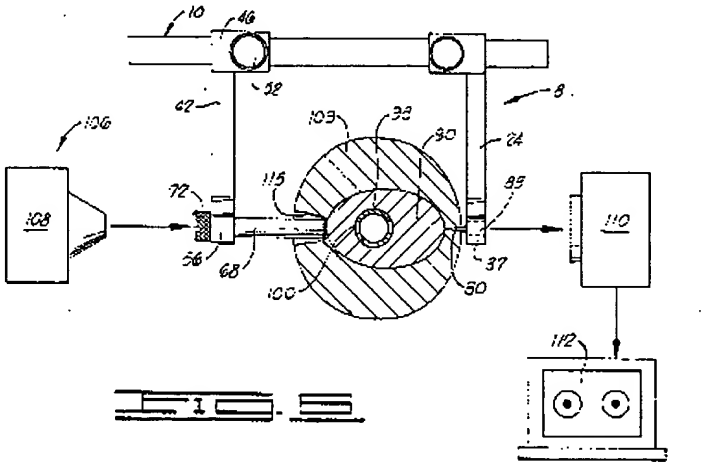
The Disclosure of the Perdue Reference

Perdue teaches methods and devices for placing screws in an orthopedic nail (98) used in setting fractures of the long bones (90) of the body. [Abstract.] First, a fluoroscope assembly (106) is used to develop an image of the screw hole(s) (100) in the nail (98) on a monitor (112). [Id.] This image enables the surgeon to adjust the fluoroscope assembly (106) until the x-rays from the fluoroscope (108) are propagated along lines which are coaxially aligned with the screw hole(s) (100) of the nail (98). [Id.]

Once lines from the x-ray correspond to the holes in the nail, a surgeon scribes reference marks, usually in the form of an "X," which correspond to the location of the screw hole(s) (100) on the limb (109) containing the fractured bone (90). [Id.] The surgeon then incises the limb (109) at the reference marks and places tubular drill guide(s) (68) of a jig (8) within the incisions such that the tubular drill guide(s) (68) are set against the bone (90) in a position of coaxial

alignment with the screws hole(s) (100) of the nail (98). [Id.] Additionally, so as to fix the location of the jig (8), pin(s) (80) are impaled into the flesh on the opposite side of the limb (109) relative to the drill guide(s) (68). [Column 11, lines 49-62.]

As illustrated in FIG. 5, reproduced below, after the tubular drill guide(s) (68) and the pin(s) (80) are positioned, the fluoroscope assembly (106) again develops an image of the screw hole(s) (100) in the nail (98) on a monitor (112). [Id.; Column 11, line 63 – Column 12, line 2.] Once the drill guide(s) 68, the screw hole(s) (100) and the pin(s) (80) are in coaxial alignment with one another, the screws are inserted through the drill guide(s) (68) and are screwed into the bone (90). [Id.]



Perdue does not Disclose the Recitations of Applicant's Claims

The Examiner does not provide specific information regarding which elements of the Perdue reference anticipate which claims and which claim elements of Applicant's invention. Rather, the Examiner provides:

> "**Claims 1, 4, 7-11, 16, 17 and 19-21:** Perdue discloses a method and apparatus where an alignment device aligns a verification or guidance device such as x-ray image device. Perdue further discloses that the device described above includes an elongated spacer element 10 having proximal and distal portions and an insert engaging element disposed on the distal portion and an alignment guide surface

> affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the insert engaging element. In addition, Perdue discloses that the device described above where the aligning of the x-ray device is used to insert prosthesis during orthopedic surgery. Moreover, the alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element and a prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced-apart from the visual indicator element (col. 7, line 46 – col. 8, line 51; col. 9, line 14 – col. 11, line 36)."

As the courts have noted, "it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Brd. of Pat. App. & Int'f. 1990) (citing Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick, 730 F.2d 1452, 1453-1454 (Fed. Cir. 1984)). As can be seen from the Examiner's vague explanation above, the Examiner has not identified where each and every facet of Applicant's claimed invention is disclosed within the Perdue reference. For this, as well as for the reasons that follow, Applicant disagrees with the Examiner's rejections.

Applicant's claim 1 recites an alignment verification device which includes an insert engaging element disposed on the distal portion and an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the insert engaging element.

Perdue does not teach an alignment verification device which includes an insert engaging element disposed on the distal portion. Rather, as can be seen from FIG. 5 of Perdue above, the distal portion of Perdue's device includes a pin which is stuck in the flesh of the patient opposed to the drill guide(s). Given that the pin neither contacts the screw or the nail, in no way does this pin act as an insert engaging element, but rather helps to stabilize the jig. Perdue also does not teach an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice spaced apart from the insert engaging element. As can be seen in FIG. 5, no where does Perdue teach a spacer element or an alignment orifice. In fact, the only orifice which Perdue teaches is an incision(s) made in the flesh of the patient where the drill guide(s) is inserted. However, these incisions are not used for alignment because they are made after the location of the holes in the nail has already been established. Accordingly, Applicant's claim 1 is not anticipated by Perdue.

Applicant's claims 2 and 5 recite an insert engaging element that is generally rectangular. In a like manner, Applicant's claim 7 recites a prosthesis engaging element that is generally rectangular. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a rectangular insert engaging element or prosthesis engaging element. Accordingly, Applicant's claims 2, 5 and 7 are not anticipated by Perdue.

Applicant's claims 3 and 6 recite an insert engaging element which includes a depth stop element. In a like manner, Applicant's claim 10 recites a prosthesis engaging element which includes a depth stop element. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a depth stop element. Accordingly, Applicant's claims 3, 6 and 10 are not anticipated by Perdue.

Applicant's claim 4 recites a device wherein the spacer element includes two elongate members with the alignment guide fixed between the elongate members, each elongate member having an insert engaging element. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a spacer element which includes two elongate members with the alignment guide fixed between the elongate members, each elongate member having an insert engaging element. Accordingly, Applicant's claim 4 is not anticipated by Perdue.

Applicant's claim 7 teaches a prosthesis alignment verification system comprising a prosthesis engaging element disposed on the distal portion and an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element and a prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device. Similarly, Applicant's claim 19 teaches a method for verifying the orientation of an image obtaining device with respect to an implanted prosthesis, comprising the steps of engaging the alignment verification device to the implanted prosthesis, the prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device.

As noted above, Perdue neither teaches an alignment verification device which includes an insert engaging element disposed on the distal portion, nor an alignment orifice (let alone one spaced apart from the insert engaging element). Perdue also does not teach a prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element.

The only visual indicator element which Perdue teaches is a reference mark, e.g., an "X," marked on the skin of the patient used for placement of the drill guides. No where does Perdue teach any type of visual indicator on the prosthesis. Contrary to any assertions made by the Examiner, the holes in the nail are not visual indicators as a surgeon, without the assistance of an x-ray, cannot see them. Perdue also does not teach a prosthesis having an engaging element configured to releasibly engage the prosthesis. Rather, Perdue teaches inserting screws in the holes of a nail. Once the screw is implanted, both the nail and the screw remain fixed in the bone, rendering any type of release engagement impossible. Accordingly, Applicant's claims 7 and 19 are not anticipated by Perdue.

Applicant's claim 8 recites a prosthesis alignment verification system wherein the engagement of the alignment verification device with the prosthesis is adapted to permit a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a system wherein engagement of the alignment verification device with the prosthesis is adapted to permit a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element. Accordingly, Applicant's claim 8 is not anticipated by Perdue.

Applicant's claim 11 recites a prosthesis alignment verification system wherein the spacer element includes two elongate members, each having a prosthesis engaging element, and the prosthesis includes two engaging elements, each configured to engage one of the prosthesis engaging elements. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a spacer element including two elongate members, each having a prosthesis engaging element, and a prosthesis including two engaging elements, each configured to engage one of the prosthesis engaging elements. Accordingly, Applicant's claim 11 is not anticipated by Perdue.

Applicant's claim 16 recites a prosthesis alignment verification system comprising a prosthesis inserter tool, the inserter tool having a prosthesis engaging element conforming substantially in shape to the prosthesis engaging element of the alignment verification device so that each prosthesis engaging element can engage the same engaging element on the prosthesis. Similarly, Applicant's claim 20 recites a method for verifying the orientation of an image obtaining device with respect to an implanted prosthesis further comprising providing an insertion tool having a prosthesis engaging element that conforms substantially in shape to the prosthesis engaging element of the alignment verification device so that the insertion tool engages the same engaging element on the prosthesis that the alignment verification device engages and engaging the prosthesis to be inserted to the insertion tool. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches an inserter tool having a prosthesis engaging element conforming substantially in shape to the prosthesis engaging element of the alignment verification device so that each prosthesis engaging element can engage the same engaging element on the prosthesis. Accordingly, Applicant's claims 16 and 20 are not anticipated by Perdue.

Applicant's claim 17 recites a prosthesis alignment verification system comprising an orientable image obtaining device including a sighting element for aiding in orienting the image obtaining device. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches an orientable image obtaining device including a sighting element for aiding in orienting the image obtaining device. Accordingly, Applicant's claim 17 is not anticipated by Perdue.

Applicant's claim 18 recites a prosthesis alignment verification system wherein the sighting element is a laser pointer. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a laser pointer. Accordingly, Applicant's claim 18 is not anticipated by Perdue.

Applicant's claim 21 recites the method wherein the alignment verification device is engaged to the prosthesis employing the same engaging element on the prosthesis from which the insertion tool was disengaged. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a method wherein the alignment verification device is engaged to the prosthesis employing the same engaging element

on the prosthesis from which the insertion tool was disengaged. Accordingly, Applicant's claim 21 is not anticipated by Perdue.

Perdue does not Inherently Anticipate Applicant's Claims

The Examiner also rejected Applicant's claims 2, 3, 5, 6, 12-15 and 18 as being inherently anticipated by Perdue. Specifically, with respect to claims 2, 3, 5, 6, 12-15, the Examiner states:

> **"Claims 2, 3, 5, 6, 12-15:** Perdue's disclosure of alignment device is used in orthopedic procedure. The spinal disc surgery is considered orthopedic procedure, therefore Perdue inherently anticipate the use of the alignment device in spinal disc prosthesis."

Contrary to the assertions by the Examiner, Perdue does not inherently anticipate Applicant's claims.

MPEP § 2112 states:

> "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic...To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient..." (internal citations and parentheticals omitted).

MPEP § 2112 continues:

> "[I]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (internal citations and parentheticals omitted).

Here, the Examiner fails to provide any basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics recited in Applicant's claims necessarily flow from the teachings of Perdue. Rather, in his rejection the Examiner states that "Perdue's disclosure of alignment device is used in orthopedic procedure...therefore Perdue inherently anticipate the use of the alignment device in spinal disc prosthesis." This cursory statement lacks any factual basis or technical reasoning and is

insufficient to meet the high standards for anticipation by inherency as required by MPEP § 2112.

Further, the Examiner erroneously likens the teachings of Perdue to Applicant's invention. Perdue discloses methods and devices for implanting a nail in a long bone while Applicant's claims are directed towards aligning a prosthesis used in orthopedic surgery. Implanting a nail in a long bone and aligning a prosthesis used in orthopedic surgery are two vastly different procedures. For example, when implanting a prosthesis in a spine, a surgeon must be very careful to ensure that the implant is placed between the vertebrae at a precise angle, lest the curvature of the patient's spine be adversely affected. To help address these concerns, Applicant teaches an insert engaging element that interacts with the prosthesis so that a sighting element can be aimed through an alignment orifice to verify the orientation of the prosthesis. Implanting a nail in a long bone does not have these same alignment concerns because the alignment of the screw in the nail is already established by the holes in the nail. Thus, Perdue would have no need to precisely determine where to place the screws in the nail. As such, it would be inconceivable to use Perdue's device when implanting a spinal disc prosthesis and Applicant's claims 2, 3, 5, 6 and 12-15 are in no way inherently anticipated by Perdue.

With respect to his rejection of claim 18, the Examiner states:

> **"Claim 18:** Perdue also discloses optical visual marker, although not explicitly stated as laser marker, to create sight line for the insertion element, which may include laser pointer (col. 11, lines 19-36)."

The Examiner's statement that "Perdue also discloses optical visual marker...which may include laser pointer" also fails to meet the high standards for anticipation by inherency as required by MPEP § 2112. Not only does this statement lacks any factual basis or technical reasoning but also "the fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that characteristic." MPEP § 2112. As noted above, nowhere does Perdue disclose a laser pointer. Rather, the only type of optical visual marker Perdue uses is an "X" marked on the patient's skin. Marking an "X" on a patient's skin does not even remotely resemble the use of a laser pointer and, as such, in no way is Applicant's claim 18 inherently anticipated by Perdue.

Accordingly, for the reasons noted above, Applicant's claims are not inherently anticipated by Perdue and therefore are allowable.

Conclusion

In view of the above, each of the presently pending claims (claims 1-21) is in immediate condition for allowance. Accordingly, the Examiner is requested to pass this application to issue.

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Respectfully submitted,

By _____

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